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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,214	06/22/2001	Hayao Tanaka	210131US0PCT	5190
22850	7590	01/11/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			AUGHENBAUGH, WALTER	
			ART UNIT	PAPER NUMBER

1772

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,214

Applicant(s)

TANAKA, HAYAO

Examiner

Walter B Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/28/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claim 12 in the Amendment filed October 20, 2004 (Amdt. C) have been received and considered by Examiner.

REPEATED REJECTIONS

2. The 35 U.S.C. 112 rejection of claim 7 that was repeated in paragraph 6 of the previous Office Action mailed April 20, 2004 has been repeated for the reasons previously made of record.
3. The 35 U.S.C. 112 rejection of claim 12 that was repeated in paragraph 7 of the previous Office Action mailed April 20, 2004 has been repeated for the reasons previously made of record in paragraph 16 of Paper 10 regarding the claimed maximum saturation absorption amount and the issue regarding "the portion of the inner surface of the container" discussed in lines 5-12 of page 5 of Paper 10 (see paragraph 16 of Paper 10).
4. The 35 U.S.C. 103 rejections of claims 6, 7 and 12 made of record in paragraphs 8-10 of the previous Office Action mailed April 20, 2004 have been repeated for the reasons previously made of record and for the following reason that addresses the amendments in claim 12 in Amdt. C: since Applicant discloses that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm² or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification) and Waki et al. disclose that copolymers containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit lack protein absorbing property (col. 1,

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lines 16-23 and 28-34), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal protein, and/or the optimal concentration range of the particular protein in solution, in order to achieve the desired saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer taught by the primary references and Waki et al. depending on the desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

NEW REJECTIONS

Claim Rejections - 35 USC § 112

5. Claims 12 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 12, does Applicant intend to claim the maximum saturation absorption amount for solely proteins or, more generally, for molecules (Applicant inserted "of protein" in the second to last line of the claim but did not delete "of molecules" in the last line of the claim)?

In regard to claim 7, the maximum saturation absorption amount claimed in claim 7 is the same maximum saturation absorption amount claimed in claim 12; since claim 7 depends upon claim 12, the maximum saturation absorption amount claimed in claim 7 is redundant.

In further regard to claim 7, if Applicant intended to limit the molecule type for the claimed maximum saturation absorption amount to solely protein in claim 12, claim 7 is broader

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than the claim that it depends upon (i.e. claim 12) since claim 7 recites that the maximum saturation absorption amount is for molecules.

ANSWERS TO APPLICANT'S ARGUMENTS

6. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 6, 7 and 12 presented on pages 4-6 of Amdt. C have been fully considered but are not persuasive.

On page 5 of Amdt. C, Applicant argues that Applicant argues that Waki et al. "does not disclose or suggest that at least an inner surface of the container is coated beforehand", but this argument is irrelevant since each of the primary references teach that the inner surfaces of the containers taught by the respective primary references are hydrophillic, as made of record in paragraphs 8-10 of the previous Office Action mailed April 20, 2004. Applicant argues that the copolymer taught by Waki et al. is "soluble in water, not insoluble in water", but the claims do not require that the polymer be insoluble in water. Applicant argues that Waki et al. do not "disclose or suggest" the claimed maximum saturation adsorption amount, but it is not stated in paragraphs 8-10 of the previous Office Action mailed April 20, 2004 that Waki et al. do "disclose or suggest" the claimed maximum saturation adsorption amount. Applicant cites the data presented in Table 5 of Waki et al. in support of Applicant's argument that "there is no reasonable expectation based on the disclosure of Waki et al that the saturation adsorption amount as presently claimed can ever be attained", but the data presented in Table 5 is for three particular proteins (i.e. albumin, γ -globulin and fibrinogen, see column headings in Table 5) at two different blood concentrations (see col. 23, lines 11-15 and the subheadings of the Table which read "Concentration of Human Plasma Protein" and "Concentration of Human Plasma Protein (1/10)": the "1/10" at the end of the second heading indicates that the blood

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concentration is diluted to one tenth the concentration of the first blood samples tested).

Absorption data for three particular proteins, each at two particular concentrations, does not represent absorption data for all proteins for all possible concentrations. Furthermore, the “absorption” property determined by Waki et al. is not the same property as the claimed saturation adsorption amount.

7. Applicant’s arguments regarding the 35 U.S.C. 112 rejection of claims 7 and 12 presented on pages 6-8 of Amdt. C have been fully considered but are not persuasive.

The saturation adsorption amount is not solely a function of the material that coats the container. Proteins that have differing degrees of hydrophilicity will have differing affinities for the material that coats the container. Applicant states that the word “saturation” in the phrase “saturation adsorption amount” makes the “saturation adsorption amount” a “fixed quantity relating to a maximum adsorption amount that a given coated surface can support irrespective of the conditions assayed”, but the saturation adsorption amount varies with the type of molecule (moreover, the particular protein). A first protein with a higher affinity for a particular coating material than that of a second protein will show a higher adsorption amount upon saturation of the protein within a given surface area of the coating material than the second protein, all other conditions being equal.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

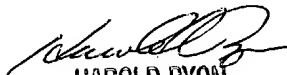
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

12/27/04 WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

1/8/05